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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

| EXAMINER |
|---|
| HUTSON, RICHARD G |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | 11 |

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/604,693 | POMPEJUS ET AL. | |
| | Examiner | Art Unit | |
| | Richard G Hutson | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Applicants preliminary amendment of claims 1, 3-7 and 34, Paper No. 10, 7/7/2003, is acknowledged. Claims 1-38 are still at issue and are present for examination.

### *Election/Restrictions*

Applicant's election without traverse of Group I, Claims 1-17, 36 and 38 in Paper No. 10 is acknowledged. Applicant's election with traverse of SEQ ID NO: 1 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the policy set forth in 1192 O.G. (Nov 19, 1996) provides that a reasonable number of sequences are allowed to be claimed in a single application, as applicants submit that ten sequences is a reasonable number of sequences to be examined in a single application (M.P.E.P. 803.04). Applicants amendment of the claims and traversal is noted, however applicants argument is not found persuasive, and applicants election of SEQ ID NO: 1 accepted. Applicants argument that in the instant application ten sequences (i.e. SEQ ID NOs) is reasonable is not found persuasive because in addition to the required sequence and text searches for each of the selected nucleotide sequences (i.e. the ten chosen SEQ ID NOs of claim 1), text and sequence searches must also be performed of each of the additional sequences which are encoded by these nucleic acid sequences (i.e. the amino acid sequences. Further multiple sequence and text databases must be searched for each sequence in order to determine the novelty of the

respective claims. As such the search and examination of more then a single of the referred to sequences would constitute an undue burden and thus it is held that the examination of the recited ten sequences is not reasonable.

With respect to applicants argument that the searches with regard to each SEQ ID NO. would be co-extensive and would not involve a serious burden on the examiner, while the searches for each of the SEQ ID NOs: may overlap, they are not coextensive and thus involve a serious burden.

It is noted that claim 37, which was originally separated from the claims of the elected Group I, has been placed with those claims of the elected Group I. The election being without traverse.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10.

***Priority***

Applicants statement on the first line of the specification to state that this application claims the priority of U.S. Provisional application 60/144448, filed July 16, 1999 and U.S. Provisional application 60/149402, filed August 17 1999, the entire contents of which are hereby incorporated by reference is acknowledged.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

No information disclosure statement is currently associated with this application.

***Specification***

The disclosure is objected to because of the following informalities:

On page 28, lines 11-14, of the specification applicants state "As used herein, the term 'hybridizes under stringent conditions" is intended to describe conditions for hybridization and washing under which nucleotide sequences at least 60% homologous to each other typically remain hybridized to each other..." Such a statement that nucleotide sequences which are 60% homologous would hybridize under stringent conditions is considered to be repugnant to what is known in the art.

Appropriate correction is required.

***Claim Objections***

Claims 1-17 and 36-38 are objected to because of the following informalities:

Claim 2 recites "RRP protein". It is suggested that the first time such a reference is made it be written out in full followed by the abbreviation in parenthesis, i.e. "DNA replication, ribosome and pathogenesis (RRP) protein".

Claim 13 recites "said cell...". It is suggested that this be amended to "said host cell..."

Claims 1-17 and 36-38 comprise nonelected subject matter (i.e. SEQ ID NOs: 5, 9, 11, 13, 15, 19, 21, 23, and 27 and the "nucleic acid molecules set forth in Appendix A").

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in that the recitation "RRP protein" is unclear. This is a separate issue from that discussed above under claim objections. Assuming that a RRP protein is interpreted as a "DNA replication, ribosome and pathogenesis (RRP) protein", the specification fails to teach which identifying characteristics distinguish such a protein from other proteins not considered to be such "RRP proteins". Thus it is unclear what applicants consider a DNA replication, ribosome and pathogenesis (RRP) protein to encompass. Claim 2 is further indefinite in that it is unclear in the recitation "RRP protein involved in the production of a fine chemical". Are those RRP proteins as

discussed above different from those RRP proteins involved in the production of a fine chemical? How does one define a fine chemical? Given these questions, the recitation "RRP protein involved in the production of a fine chemical" is confusing, vague and thus indefinite. Further as applicants have elected to examine SEQ ID NO: 1, and thus the claims are examined with respect to SEQ ID NO: 1, it is unclear if SEQ ID NO: 1 is considered by applicants to be included as a "RRP protein" because the only reference to SEQ ID NO: 1 is in TABLE 1: Genes in the Application, where SEQ ID NOs: 1-30 are not included with those genes involved with "DNA replication, topology, and packaging" , "Ribosomal Genes", or "Genes involved in Pathogenesis". Thus it is unclear what applicants consider to be a "RRP protein" and further if SEQ ID NO: 1 is considered to be a "RRP protein" .

Claim 8 is indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While page 28, lines 11-14, of the specification states "As used herein, the term 'hybridizes under stringent conditions" is intended to describe conditions for hybridization and washing under which nucleotide sequences at least 60% homologous to each other typically remain hybridized to each other..." Such a statement that nucleotide sequences which are 60% homologous would hybridize under stringent conditions is considered to be repugnant to what is known in the art, however given applicants statement, this is how the claim is interpreted.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-9 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5-9 are directed to all possible nucleic acid molecules which encode a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein said nucleic acid molecule hybridizes to SEQ ID NO: 1 under the defined conditions (claim 5), or those nucleic acid molecules which are merely 50% identical to or comprise a fragment of 15 nucleotides of SEQ ID NO: 1 (claims 6 and 7) or those nucleic acid molecules which hybridize to any of the nucleic acid molecules of claims 1-7 (claim 8) or comprise a portion thereof SEQ ID NO: 1 (claim 9). Claims 36-38 are directed to all possible host cells comprising a nucleic acid molecule of SEQ ID NO: 1, wherein the nucleic acid molecule is disrupted (claim 36), comprises one or more modifications (claim 37) or the regulatory region of the nucleic acid molecule is modified relative to the wild-type regulatory region of the molecule (claim 38).

The specification, however, only provides a single representative species isolated from *Corynebacterium glutamicum* encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these nucleic acid molecules by any identifying structural characteristics or

properties. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. It is noted that applicants claims read on a genus of nucleic acid molecules and host cells comprising said nucleic acid molecules, wherein the nucleic acid molecules have no functional limitations, relatively minor structural limitations and thus absolutely no structure to function/activity relationship.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

***Claim Rejection(s) - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17 and 36-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-4 and 8-17 are drawn to those nucleic acid molecule which encode a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, and vectors and host cells comprising said nucleic acid molecule and methods of expression of said nucleic acid molecule. Claims 5-8 are drawn to those nucleic acids which encode allelic variants of SEQ ID NO: 2 or those which are 50% identical to or comprise a mere 15

contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 1. Claims 5-8 are drawn to those nucleic acids which encode allelic variants of SEQ ID NO: 2 or those which are 50% identical to or comprise a mere 15 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 1. Claims 36-38 are drawn to those host cells comprising a nucleic acid molecule of SEQ ID NO: 1, wherein the nucleic acid molecule is disrupted (claim 36), comprises one or more modifications (claim 37) or the regulatory region of the nucleic acid molecule is modified relative to the wild-type regulatory region of the molecule (claim 38).

The claimed nucleic acid molecules and host cells are not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence being claimed. Further, the claimed nucleic acid molecule is not supported by a substantial utility because the specification states only that the nucleic acid molecules are useful for the identification of microorganisms which can be used to produce fine chemicals, the modulation of fine chemical production in C. glutamicum or related bacteria, the typing or identification of C. glutamicum or related bacteria, as reference points for the mapping the C. glutamicum genome and as markers for transformation. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the encoded proteins that are to be produced as final products resulting from processes involving the claimed nucleic acid molecules have asserted or identified specific and substantial

utilities. The research contemplated by applicants to characterize potential ligand and protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the encoded proteins or associated ligands or the mechanism in which proteins or ligands are involved in the production of fine chemicals does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid molecules such that another non-asserted utility would be well established for the compounds.

Claims 1-17 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed above under the rejection under 35 U.S.C. 101, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al. (U.S. Patent No. 6,551,795 B1).

Rubenfield et al. teach an isolated nucleic acid molecule comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO: 1, which comprises at least 17 contiguous residues of SEQ ID NO: 1 (see specifically residues 217-233 of instantly disclosed SEQ ID NO: 1 compared to residues 1874 through 1895 of SEQ ID NO: 3845 of U.S. Patent No. 6,551,795 B1). Further the taught nucleic acid molecule of Rubenfield et al. would hybridize to itself under stringent conditions and comprises at least a portion thereof the nucleic acid molecule of claim 1, as a single nucleotide is a portion of SEQ ID NO: 1. Thus claims 7-9 are anticipated by Rubenfield et al.

**Remarks**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh